REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Status of Claims:

Claims 28-67 and 70-86 were previously withdrawn due to a restriction, and are cancelled without prejudice.

Claims 1, 9, and 68 are amended. Claims 6 and 8 are cancelled. Claims 87-95 are added as new claims. Hence, claims 1-5, 7, 9-27, 68-69, and 87-97 are presented for examination.

Claim Objections:

Claims 9 and 12 are objected to for being self-depending. Claim 9 has been amended to be dependent on claim 1; and claim 12 is dependent on claim 9.

Claim Rejections:

Claims 1, 9, 11-16, and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker et al (U.S. Patent No. 4,994,047). Claims 2 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Ash et al (U.S. Patent No. 6,042,561). Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Ash et al, and further in view of Brange et al (U.S. Patent No. 4,472,385). Claims 3 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Brange et al. Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Brange, and further in view of Nelson (U.S. Patent No. 5,702,372). Claims 6, 7, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of LeVeen et al (U.S. Patent No. 4,448,195). Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Burnham (U.S. Patent No. 4,764,324). Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of LeVeen et al or Hurnham, and further in view of Nelson. Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Ekwuribe et al (U.S. Patent No. 6,309,633).

With respect to claims 1-5, 7, 9-27, 68-69, in view of the current amendments, the above referenced rejections are respectfully traversed.

As amended, claim 1 recites a stabilizing catheter for protein drug delivery to a user comprising a tubing including at least one layer, wherein the at least one layer includes one or more materials that reduce diffusion of small molecules through the tubing, and wherein the one or more materials of the at least one layer includes materials selected from at least polytetrafluoroethane, saran (PVOC), polysulfone, hydrophilic glass, derivatives of these materials, and mixtures of these materials.

Neither Walker (U.S. 4,994,047) nor any other cited reference teach the use of materials selected from at least polytetrafluoroethane, saran (PVOC), polysulfone, hydrophilic glass, derivatives of these materials, and mixtures of these materials.

LeVeen (U.S. 4,448,195) teaches the use of a glass fiber netting structure for reinforcement of the catheter. (LeVeen, col. 2, lines 45-49.) LeVeen does not teach the use of hydrophilic glass as specified in applicant's invention. (Specification, page 28, lines 1-2.) Hydrophilicity can provide significant advantages in a catheter for protein drug delivery, by decreasing the likelihood of the proteins adhering to the inside surfaces of the catheter causing denaturing of the protein drug. (Specification, page 2, lines 18-28, and page 4, lines 6-9).

Furthermore, the requirements of the hydrophilic material in Walker suggests away from a combination with LeVeen. Walker teaches a catheter with a hydrophilic layer that swells and softens upon contact with an aqueous liquid by absorbing the liquid. (Walker, col. 3, lines 4-7, and col. 4, lines 6-9). For the hydrophilic material in the hydrophilic layer, Walker specifies that the preferable softening ratio to be at least 2:1 after hydration. (Walker, col. 4, lines 42-45). As examples, Walker teaches the use of swelling and softening polymers. (Walker, col. 4, lines 46-50). Although some glass can by hydrophilic, glass is not normally known to absorb liquids and swell or soften as required by Walker. Therefore, hydrophilic glass is not compatible with the use of the hydrophilic material as required by Walker. Hence, the swelling and softening requirements of Walker catheter material teach away from using LeVeen's glass material in Walker's catheter structure.

Since none of the references teach or suggest the materials of polytetrafluoroethane, saran (PVOC), polysulfone, or hydrophilic glass, it is submitted that claim 1 is patentable over the cited references. Because claims 2-27 are dependent claims of claim 1, they are deemed allowable as well.

As amended, claim 68 recites a stabilizing catheter comprising a hydrophilic coating on an innermost surface of the tubing formed from one or more hydrophilic protein compatible materials.

Walker teaches a swellable cannula with a hydrophilic layer and a substantially non-hydrophilic layer, wherein the hydrophilic layer comprises at least two-thirds (2/3) of the cross-sectional area of the wall of the cannula. (Walker, abstract). In Walker, the hydrophilic layer can be the outer or inner layer, and swells and softens upon contact with an aqueous liquid by absorbing the liquid. (Walker, col. 3, lines 4-7, and col. 4, lines 6-9). The hydrophilic layer in Walker is not a coating, but comprises a separately formed structure that comprises the bulk of the cross-sectional area of the cannula. Walker teaches co-extruding both the hydrophilic layer and the non-hydrophilic layer simultaneously, further showing that the hydrophilic layer is a separately formed structure and not a coating. (Walker, col. 9, lines 18-20.) In contrast, claim 68 recites that the hydrophilic layer is a coating on the innermost surface of the tubing and, thus, must be formed after the formation of the tubing. (Specification, page 20, lines 1-13).

Moreover, Walker is only concerned with the physical properties of the hydrophilic materials, hence the only requirements for the hydrophilic materials are properties such as liquid absorption ratio and softening ratio. (Walker, col. 4, lines 23-45). By comparison, claim 68 of the present application restricts the material for the hydrophilic coating to protein compatible materials. The hydrophilic coating aims to resolve the problem of protein molecules sticking to the inner surfaces of the catheter, causing denaturing of the protein drug and "site loss". (Specification, page 2-3, lines 18-28 and 1-3). Protein molecules react differently to different hydrophilic materials, and not all hydrophilic materials are "protein-compatible" and suitable as a material for the hydrophilic coating. (Specification, page 21, lines 15-27). There is no teaching or motivation in Walker to use a protein-compatible hydrophilic material.

Therefore, since Walker does not teach a hydrophilic coating using a protein-compatible material, it is submitted that claim 68 is not anticipated by Walker under 35 U.S.C. 102(b).

Similarly, claim 13 (dependent on claim 1) teaches "an innermost layer that is formed from one or more hydrophilic protein compatible materials". Because Walker does not teach the requirement of using a protein-compatible hydrophilic material, claim 13 is patentable over Walker for this reason in addition to the reasons stated above for independent claim 1.

In addition, to further distinguish the cited references, claim 87 of the present application recites that the hydrophilic coating comprises materials applied to the innermost surface of the tubing through a surface treatment. As described in the specification, a surface treatment produces a thin and uniform hydrophilic coating. (Specification, page 20, lines 1-13). This further distinguishes against the thick swellable layer in Walker, and therefore claim 87 is allowable for this reason in addition to the reasons stated above for claim 68.

Claim 88 recites that the hydrophilic coating composes materials applied onto the innermost surface of the tubing after the formation of the at least one layer, which further distinguishes Walker where hydrophilic and non-hydrophilic layers are co-extruded. Claim 89 recites that the thickness of the hydrophilic coating is less than that of the first layer. This further distinguishes Walker, where the hydrophilic layer comprises 2/3 of the total cross-sectional area of the cannula. Claims 90-91 recites materials for the hydrophilic coating, none of which is taught by Walker. Hence, claims 88-91 are allowable over Walker for these reasons in addition to the reasons stated above for claim 68.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or

credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date: April 13, 2006

By: _____

Ted R. Rittmaster
Attorney for Applicant
Registration No. 32,933

FOLEY & LARDNER LLP
Customer Number: 23392
Telephone: (310) 975-7963
Facsimile: (310) 557-8475